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10/576,857	10/07/2008	Hans Lennernas	02314-26109.PCT.US	8109

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EXAMINER	
AL-AWADI, DANAH J	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
01/21/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/576,857	LENNERNAS ET AL.	
	Examiner	Art Unit	
	DANAH AL-AWADI	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *73-89 and 92-145* is/are pending in the application.

4a) Of the above claim(s) *117-145* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *73-89 and 92-116* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Receipt of Applicants arguments/remarks filed 11/03/2010 is acknowledged.

The Examiner acknowledges the following:

Claims 73 and 116 been amended.

Claims 90 and 91 are cancelled.

INFORMATION DISCLOSURE STATEMENT

2. No new Information Disclosure Statements (IDS) has been submitted for review.

WITHDRAWN REJECTIONS

3. The rejection to claims 73, 76-89, 93-99, and 107-115 , under 35 USC 103(a) as being unpatentable over Royer Garfield (US 2003/0170307) is moot in view of the newly applied rejection.

The rejection of claims 74 and 75 under 35 USC 103(a) as being unpatentable over Royer Garfield (US 2003/0170307) in view of Stupak (US Patent 5, 162, 117) is moot in view of the newly applied rejection.

The rejection of claims 100-106 , under 35 USC 103(a) as being unpatentable over Royer Garfield (US 2003/0170307) in view of Ashton (US 2003/0158598) is moot in view of the newly applied rejection.

Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

4. Upon further consideration the following rejections are new:

NEW REJECTIONS

Claim Rejections- 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 73-89, 92-116 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims use broad genus claims such as derivative. For example, an androgen derivative composition is claimed. The extremely broad genus terms "derivative of androgen", "derivative of anti-androgen", "derivative of oestrogen," "derivative of anti-oestrogen",

"derivative of gestagen", "derivative of anti-gestagen", "derivative of progestagen", " a gonadotropin-releasing hormone or an analogue or derivative thereof", and derivative of gonadotropin inhibitor", do not have sufficient description in the specification, nor are a representative number of compounds described within any one of these genii to demonstrate that applicant was in possession at the time of filing of any one of these genus terms.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co. the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Fiers, 984 F.2d at 1171, 25 USPQ2d 1601; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus …") Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not

constitute a representative number of species to adequately describe a broad generic. In Gostelli, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a prima facie case are discussed below.

In the instant case, the claims are drawn to a pharmaceutical composition comprising i) one or more biodegradable hydrating ceramics ii) one ore more expandable agents, wherein the expandable agent is present in the composition at a concentration of at least about 0.1% w/w to about 10% w/w, iii) a sorbed aqueous medium, wherein the sorbed aqueous medium is present in the composition at a concentration of at the most about 30% w/w to about 60% w/w of the total composition, and iv) one ore more therapeutically and/or diagnostically active substances, which is an androgen or derivative thereof, an anti-androgen or derivative thereof, an oestrogen or derivative thereof, an anti-oestrogen or derivative thereof, a gestagen or derivative thereof, an anti-gestagen or derivative thereof, an oligonucleotide, a progestagen or derivative thereof, a gonadotropin-releasing hormone or an analogue or derivative thereof, a gonadotropin inhibitor or

a derivative thereof, an adrenal and/or prostate enzyme inhibitor, a membrane efflux and/or membrane transport protein, an immune system modulator, an angiogenesis inhibitor, or combinations thereof, which in solid form has ruptured structure.

(1) Level of skill and knowledge in the art:
The level of ordinary skill in the art is high.

(2) Partial structure:
Derivative is not defined in the specification so it is not clear how it is related to the therapeutic agents claimed and what is meant by derivative. It is not shown how to make and use such derivatives and the possibilities are endless.

(3) Physical and/or chemical properties and (4) Functional characteristics:
Applicant has not set forth the physical and/or chemical properties and functional characteristics for derivatives of the claimed therapeutics.

(5) Method of making the claimed invention:
No derivative description how to make the claimed therapeutics exists in the application.

As stated supra, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that the claims are broad and generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless to any derivative of the claimed therapeutics. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the

compounds beyond those compounds specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of the claimed therapeutics and compounds identified in the specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

5. Claim 116 is a rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification, while being enabled for therapeutically and diagnostically active substances, does not reasonably provide enablement for prophylactically active substances. Applicant's specification is enabled for diagnostically active substances and therapeutically active substances, but is not enabled for the preventative agents.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (Wands, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." Wands, 8 USPQ2d 1404. Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

(A) The nature of the invention:

The invention is drawn to a composition comprising i) hydrating ceramics ii)expandable agents iii)a sorbed aqueous medium and iv)one or more therapeutically, prophylactically, and/or diagnostically active substances.

To prevent means to keep from occurring and the term implies that a condition will not occur, not just that the severity of the symptoms associated with the disease are reduced or that the onset of the condition is delayed.

(B) The breadth of the claims:

The invention is drawn to a composition comprising i) hydrating ceramics ii)expandable agents iii)a sorbed aqueous medium and iv)one or more therapeutically, prophylactically, and/or diagnostically active substances.

(C) The state of the prior art:

The state of the art is very high in terms of therapeutic and diagnostically active substances. There is no evidence in the prior art that the instant composition would be usable as a preventative composition.

D) The predictability or unpredictability of the art:

There is no evidence in the prior art that the instant composition would be usable as a preventative composition

(E) The relative skill of those in the art: The level of ordinary skill in the art is high.

(F) The amount of direction or guidance presented: There is nothing in the specification that would indicate that the current invention prevents pain or inflammation from the medical conditions cited. No guidance for the preventative therapeutics is provided in the specification

The amount of direction or guidance is minimal or non-existent with regards to preventative drugs. Thus with respect to the instant composition, there is a substantial gap between treatment with therapeutics and prevention. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap.

(G) The presence or absence of working examples: The specification does not disclose any evidence that the specific substances lead to prevention.

(H) The quantity of experimentation necessary: In the instant case, there is a substantial gap between treatment and prevention in the case of preventative drugs. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap.

CONCLUSION

Given the complete lack of direction in applicant's instant disclosure, the amount of experimentation required to realize the full scope of claims 116 is clearly undue.

Claim Rejections- 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 73, 76-89, 92-99, and 107-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over (Royer Garfield US 2003/0170307), Wise et al. (WO 03/065996) and Li et al. (US Patent 6, 479, 418).

With regards to pending claim 73, US Royer Garfield (2003/0170307) (hereafter Royer) discloses a pharmaceutical composition comprising biodegradable hydrating ceramics (i.e. calcium sulfate), a expanding agent (sodium bicarbonate), a sorbed aqueous medium, and an bioactive agent such as anti-inflammatory agents ([0016], [0021], [0094]). Royer teaches that the composition can be injected with subsequent formation of a solid in vivo ([0021]). Royer teaches that the matrix has a porosity ([0037]). This reads on having a ruptured foam-like structure.

With regards to claim 81 which states in solid form has a ruptured structure obtained by disintegration into two or more parts, this is a product by process limitation and given little patentable weight for claims directed to the product.

Royer teaches calcium sulfate in the form of a powder (Example 13, paragraph [0143]). Royer further teaches that the powder has a mean particle size of less than 50 microns.

Royer teaches sodium bicarbonate which as evidenced by the specification is a gas-forming expandable agent (Example 15). Furthermore, sodium bicarbonate is well known in the art to act as a expandable agent as evidenced by Wise et al. (WO 03/065996) (hereafter Wise) (lines 29-31 p. 4 and lines 9-13 p. 9) .

Royer teaches the inclusion of polyethylene glycol (Example 13).

Royer teaches having a shape of beads (paragraph [0072]).

Royer teaches the matrix has a porosity and that the particle sizes measure in microns which reads on having a microporous structure.

With regards to the limitation that the active agent is homogenously dispersed, the prior art does not teach this, however it teaches that the active agent is dispersed and it would have been obvious to the skilled artisan to homogenously disperse the active agent to obtain an even distribution of the active agent.

With regards to the expandable agent is present at a concentration of at least about 0.1% w/w to about 10%, and the limitation wherein the sorbed aqueous medium is present in the composition at a concentration of about 30% w/w to about 60% w/w of the total composition; absent evidence of criticality, since the vales of each parameter with respect to the claimed composition are adjustable, it would have been prima facie obvious for a person having ordinary

skill in the art to routinely optimize the amount of each parameter in the composition and adjust the concentrations of the expandable agent and sorbed aqueous medium. One would have been motivated to do so because sodium bicarbonate is known in the art to be a suitable expandable agent as Wise teaches the sodium bicarbonate is responsible for expansion. Table 1 of Wise teaches adding an amount of sodium bicarbonate within the claimed range. It would be obvious to the skilled artisan to optimize this range for desired porosity and expansion. Furthermore, Li et al. (US Patent 6, 479, 418) (hereafter Li) additionally teaches that controlled use of foaming agents (i.e. sodium bicarbonate) up to 10% enables the skilled artisan to obtain desired porosity (lines 21-36 col. 4).

With regards to the sorbed aqueous medium, Royer teaches that calcium sulphate (hemihydrate) takes up water and crystallizes as the higher hydrate and that unadulterated calcium sulfate matrix exhibits poor drug release profiles (¶ 0035). Royer further teaches that the matrix polymer is routinely used as a solution (¶ 0067) and that the concentration of the matrix biopolymer ranges from 0.1% to 50% (¶ 0068) which falls within the claimed range. Furthermore, availability of water is used as a means to control the rate of solidification (¶ 0070). It would be obvious to the skilled artisan to optimize the amount of sorbed aqueous medium to control the rate of solidification.

With regards to the limitations of the %w/w of the active substance contained in the composition being released during specific time frames after implantation into a human; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed towards the composition is instantly claimed.

Furthermore, these are functional limitations of the composition and it would be expected that the composition would exhibit these properties when in vivo.

With regards to the limitations claiming the percent of openings having a maximum width, absent evidence of criticality, since the vales of each parameter with respect to the claimed composition are adjustable, it would have been prima facie obvious for a person having ordinary skill in the art to routinely optimize the amount of each parameter in the composition and adjust the amount of openings and the width of them.

With regards to the surface area of the composition; absent evidence of criticality, since the vales of each parameter with respect to the claimed composition are adjustable, it would have been prima facie obvious for a person having ordinary skill in the art to routinely optimize the amount of each parameter in the composition and adjust the surface area. Royer teaches that the shape affects surface area and that as for example beads get smaller, the surface area per given volume increases. Small beads deliver drugs faster than larger (¶ 0085 and ¶ 0088).

Royer does not explicitly state the route of delivery is parenteral, however this is intended use and give little patentable weight. Furthermore, the composition of Royer, absent evidence to the contrary, would be capable for parenteral delivery.

7. Claims 74 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Royer Garfield (US 2003/0170307) Wise et al. (WO 03/065996), and Li et al. (US Patent 6, 479, 418) as applied to claims 73, 76-89, 92-99, and 107-115 above, and further in view of Stupak et al. (US Patent 5, 162, 117).

Royer does not teach the specific active agents flutamide, hydroxyl-flutamide, cyproteron, nilutamide, or bicalutamide, however, Stupak et al. (US Patent 5, 162, 117) (hereafter Stupak) teaches controlled release of flutamide which can be combined with calcium sulfate (column 3, lines 35-44).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute flutamide as the medicinal in Royer. One would have been motivated to do so because Royer teaches the inclusion of medicinal such as antineoplastics and Stupak teaches that flutamide is a proven potent antiandrogen approved for the treatment of advanced prostate cancer (paragraph of line 20 column 1)

8. Claims 100-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Royer Royer Garfield (US 2003/0170307), Wise et al. (WO 03/065996), and Li et al. (US Patent 6, 479, 418) as applied to claims 73, 76-89, 92-99, and 107-115 above, and further in view of Ashton et al. (US 2003/0158598).

Royer does not teach a pore-sealing agent, however with regards to the composition including pore-sealing agents, Ashton et al. (US 2003/0158598) (hereafter Ashton) teaches impregnating pores of a polymer matrix. The pores are impregnated with additives that are bioerodable and water-soluble. Contact with physiological fluid will dissolve the bio-erodible additives and enlarge the pores size of the polymer matrix increasing the surface area of the polymer matrix exposed to physiological fluid, thereby exposing the drug to the environment and accelerating release (paragraph [0127]). This will allow the drug to diffuse out of the polymer matrix more readily. These pore filling additives include PEG, hyaluronic acid.

It would have been prima facie obvious to one of ordinary skill in the art to include pore-sealing agents. One would have been motivated to do so to obtain controlled release of an active agent. Ashton does not teach the specific pore-forming agents of pending claims 103, and 105, however the prior art recognizes the advantages of utilizing a pore-sealing agent and it would have been obvious to the skilled artisan to substitute one pore-sealing agent for another.

With regards to the concentration and amounts of pore-sealing agent; absent evidence of criticality, since the vales of each parameter with respect to the claimed composition are adjustable, it would have been prima facie obvious for a person having ordinary skill in the art to routinely optimize the amount of each parameter in the composition and adjust concentration of the pore-sealing agent to adjust the controlled release of an active agent. Furthermore, MPEP 2144.05 states, ""where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine optimization."

CORRESPONDENCE

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danah Al-awadi whose telephone number is (571) 270-7668. The examiner can normally be reached on 9:00 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be

obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DA/
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615